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## **AUDIT REPORT FOR NORTHERN IRELAND**

### **MAY 17 THROUGH 23, 2000**

January 23, 2001

## **INTRODUCTION**

### **Background**

This report reflects information that was obtained during an audit of Northern Ireland's meat inspection system from May 17 through 23, 2000. The establishment certified to export meat to the United States (#9014) was audited. There was no slaughter at this facility: only processing operations were conducted. Two establishments had been certified for U.S. export when this audit was planned; the management of one of these (Establishment #9056) elected to withdraw its eligibility for the United States several days prior to its scheduled audit by FSIS. The auditor was informed by the Department of Agriculture and Rural Development in Northern Ireland (DARDNI) officials that there were no plans to undertake to reinstate Est. 9056's certified status within the foreseeable future.

The last audit of the meat inspection system of Northern Ireland was conducted in February 1999. Two establishments were certified for U.S. export at that time; both were audited and were found to be acceptable. No deficiencies were reported.

Deficiencies identified during this new audit included an inadequate maintenance and cleaning program for product-contact equipment, unreliable timeliness of reporting of results and corrective actions following unsatisfactory water potability checks, and lack of pre-shipment document reviews.

Importation of beef or beef products was not allowed at the time of this audit due to the presence of Bovine Spongiform Encephalopathy (BSE) in the United Kingdom. The only restriction on pork products was that the product must be indigenous and processed in a dedicated establishment that receives no animals from countries where Swine Vesicular Disease exists (these conditions were fulfilled in Northern Ireland).

In 1999, one establishment (9014) exported 2,400 lbs. of cured pork and pork sausage to the U.S. In the first 4 months of 2000, this establishment exported 29,948 lbs. of cured pork and pork sausage to the U.S.; there were no rejections at U.S. ports of entry.

## **PROTOCOL**

This on-site audit was conducted in four parts. One part involved visits with national meat inspection officials of Northern Ireland to discuss oversight programs and practices, including enforcement activities. The second entailed an audit of a selection of records in the meat inspection headquarters facilities preceding the on-site visits. The third was conducted by an on-site visit to the establishment. The fourth involved visits to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence of microbiological contamination with *Salmonella*.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of Hazard Analysis and Critical Control Point (HACCP) systems and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Northern Ireland's inspection system was assessed by evaluating these five risk areas.

During the on-site establishment visit, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

## RESULTS AND DISCUSSION

### Summary

Based on the performance of the single establishment, Northern Ireland's "In-Plant Inspection System Performance" was evaluated as In-Plant System Controls In Place.

Effective inspection system controls were found to be in place in the establishment; it was recommended for re-review. Details of audit findings, including compliance with HACCP and SSOP programs are discussed later in this report.

### Entrance Meeting

On May 17, an entrance meeting was held at the Belfast offices of the Department of Agriculture and Rural Development for *Northern* (DARDNI), and was attended by Dr. Robert M. McCracken, Chief Veterinary Officer (CVO); Dr. Robert Houston, Deputy CVO; Dr. Robert Huey, Divisional Veterinary Officer; Dr. Liam McNiel, Veterinary Officer; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. Topics of discussion included the following:

1. The audit itinerary and lodging accommodations were discussed.
2. The auditor provided the DARDNI officials with a printed copy of the latest quarterly enforcement report and informed them how to access the information via the FSIS homepage, and inquired whether Northern Ireland makes similar data available to the public; the officials replied that there was, as yet, no publication of enforcement actions by DAFRD on the internet, although there were plans to offer it in the foreseeable future. Two monthly periodical publications for the U.K., one for BSE and one for a Hygiene Assessment System (HAS), were available to the general public.

3. The auditor provided copies of the data-collection instruments that would be used during the establishment audit for SSOPs and the HACCP program.
4. The auditor gathered data to update the country profile for Northern Ireland.

### Headquarters Audit

An overview of the organizational structure of Northern Ireland's inspection system was presented.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audit of the establishment be led by the inspection official that normally conducts the periodic reviews for compliance with U.S. specifications. The FSIS auditor (herein-after called "the auditor") observed and evaluated the process.

The auditor conducted a review of inspection system documents at the headquarters of the inspection service. This records review focused primarily on food safety hazards and included the following:

- Internal audit reports
- Supervisory visits to the establishment that was certified to export to the U.S.
- Training records—inspectors/lab personnel
- Enforcement actions
- Consumer complaints/Recalls
- Product seizures and similar actions
- Export certificates

No concerns arose as a result the examination of these documents.

### Government Oversight

All inspection veterinarians and inspectors in the establishment certified by Northern Ireland as eligible to export meat products to the United States were full-time Veterinary Service employees, receiving no remuneration from either industry or establishment personnel.

### Establishment Audit

Two establishments were certified to export meat and/or poultry products to the United States at the time this audit was planned. One of these (Est. 9056) relinquished its U.S. certification several days before it was due to be audited. Government inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products in the remaining establishment (9014).

## Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information was also collected about intra-laboratory quality assurance procedures, including sample handling, and methodology.

The Veterinary Sciences Division Laboratory in Stormont, Belfast was audited on May 22, 2000. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable. Unknown intra-laboratory check samples were performed together with all routine field sample analyses, which were being run at least once per month.

Northern Ireland's microbiological testing for *Salmonella* was being performed in DARDNI's Food Microbiology / Food Science Division Laboratory, which was audited on May 22. No concerns arose as a result of this audit.

## Establishment Operations

The operations conducted at Establishment 9014 were beef, pork, and lamb boning and fresh/frozen sausage production and (not for U.S. export) pressed and sliced pork liver. As stated above, no beef was exported to the U.S. due to the presence of BSE.

## SANITATION CONTROLS

Based on the on-site audit of the establishment, Northern Ireland's inspection system had controls in place for chlorination procedures; back-siphonage prevention; hand-washing facilities; sanitizers; pest control and monitoring; temperature control; lighting; operational and inspectors' work space; ventilation; over-product ceilings; dry-storage areas; welfare facilities; outside premises; personal dress, habits, and hygiene practices; prevention of cross-contamination; equipment sanitizing; product reconditioning; operational sanitation; and waste disposal.

### Sanitation Standard Operating Procedures (SSOPs)

The establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements, with the following exceptions:

### Pre-Operational Sanitation and Product Contact Equipment

The maintenance and cleaning program for product contact equipment was found to be deficient. Many plastic edible product trays had cracked and broken edges, and were in need of repair or replacement. Two of the four large stainless combo bins had cracked and broken edges, one plastic liner was torn, providing inadequate protection of the product it contained, and grease was found on the edges of the combo bins. The conveyor belt for bones, which was positioned directly above exposed product work areas, was grossly deteriorated, with heavily frayed edges and a deeply gouged surface. This was not in itself a problem, but the stainless steel trough between it and the work area left the first foot of this conveyor belt completely exposed over the production area. Also, there were several significant gaps in this trough. Black debris was found on the majority of cutting boards and stainless steel product-contact surfaces in the production area before the start of operations. DAFRD officials took immediate corrective actions, ensuring that all affected equipment was properly cleaned and sanitized before the start of operations, and prompt repair/ replacement of deteriorated equipment was scheduled.

### Water Potability Controls

A routine water sample was taken from the tap in the boiler room on Wednesday, June 29, 1999. The sample was received in the laboratory the same day and was tested the following day. The result was unsatisfactory, due to a high (>3,000) total plate count at 37°C. The results were mailed (there was no telephone call or fax notification) on July 5, to the inspection team, which was based in an nearby slaughter facility, and were received by them a day or two later. The veterinarian immediately called the laboratory in Belfast and requested a new sample. No product was retained. The quality control person, as soon as she received (by fax) a copy of the information from the policy division of the inspection service, called the veterinarian and was told that he had taken action. Re-sampling of water from the same source, and also from the water main entering the establishment, was not done until July 22. These samples were received in the lab the same day and tested the following day. The results were satisfactory and were reported via the postal service three days later. A total of 19 days had elapsed from the laboratory's determination that the water sample was unacceptable until the inspection service received the satisfactory report.

Another routine water sample was taken from the tap in the canteen on Thursday, April 27, 2000. The sample was received in the laboratory the same day and was tested the following day. The result was unsatisfactory, due to a high (>3,000) total plate count at 22°C. The results were mailed (there was no telephone call or fax notification) on May 1, to the inspection team, which is based in an nearby slaughter facility. This was received by them a day or two later. The veterinarian called the lab in Belfast on May 15 and requested a new sample, and called the quality assurance person to inform her and to say that he had requested a follow-up sample. No product was retained. Re-sampling was not done until May 17, of water from the same source and also in the boning room. No product had been retained. At the time of this audit, the results were still pending.

The efficiency of the reporting procedures and controls to ensure that prompt corrective actions are taken in the event of unacceptable water test results were discussed during the

country exit meeting. An improved, reliable system of reporting of results and corrective action was developed and implemented within several days of the establishment audit.

### Documentation

Pre-operational sanitation activities were adequately documented, but documentation of operational sanitation activities needed improvement.

## ANIMAL DISEASE CONTROLS

Northern Ireland's inspection system had controls in place to ensure adequate condemned and restricted product control and procedures for sanitary handling of returned and rework product. No slaughter establishments were certified as eligible to produce for export to the United States at the time of this audit. All pork used in U.S.-eligible product originated at Est. 332, in the Republic of Ireland. This establishment was certified to produce product for export to the United States.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit.

There was a system of full identification and tracking of movement of all bovines from birth to death, called the Animal and Public Health Information System (APHIS), which replaced the Animal Health Computer in 1998. This was demonstrated for the auditor. Information was also being provided to DAFRD by veterinarians at all sale barns and when doing tuberculin testing.

## RESIDUE CONTROLS

Northern Ireland's National Residue Testing Plan for 2000 was being followed, and was on schedule. The inspection system of Northern Ireland had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

## SLAUGHTER/PROCESSING CONTROLS

The inspection system of Northern Ireland had controls in place to ensure adequate pre-processing trim, processed product re-inspection, identification of ingredients, formulations, packaging materials, laboratory confirmation, label approvals, inspector monitoring, processing equipment, and post-processing handling.

## HACCP Implementation

All establishments approved to export meat products to the U.S. are required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic

inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were found to meet the basic FSIS regulatory requirements, with one exception: no formal pre-shipment reviews were being performed. This requirement was explained in detail during the exit meetings in the establishment and at the headquarters offices in Belfast, and was to be implemented immediately.

## ENFORCEMENT CONTROLS

### Inspection System Controls

The DARDNI inspection system controls [control of restricted product and inspection samples, processed meat re-inspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls (including the taking and documentation of corrective actions under HACCP plans), inspection supervision and documentation, the importation of only eligible live-stock from other countries (i.e., only from eligible countries and certified establishments within those countries), and the importation of only eligible meat or poultry products from other countries for further processing] were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

### Testing for *Salmonella* Species

The processing establishment was not required to perform *Salmonella* testing (no ground meat was produced as a final product). Northern Ireland had implemented the same *Salmonella* testing program, as described in the PR/HACCP final rule, for the slaughter facility, which had voluntarily relinquished its U.S. certification.

### Species Verification Testing

At the time of this audit, Northern Ireland was not exempt from the species verification testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

### Monthly Reviews

There were two internal reviewers, called Regional Veterinary Managers. Both were veterinarians with at least 5 years' experience in establishments, and similar time in headquarters policy positions. All had had special instruction and ongoing training in foreign requirements, and were being provided promptly with copies of new information by Dr. Robert Huey, Divisional Veterinary Officer, Policy.

Each establishment listed for U.S.-eligibility was being reviewed, by either one or the other of the two reviewers, once per month. Other meat establishments in Northern Ireland were also reviewed, but not monthly. None of the reviews of the U.S.-eligible establishments were announced to the establishment management, but some were announced to the inspection personnel (one day in advance).

One copy of each report generated by the internal reviewers was maintained on file in the establishment, one was retained by the internal reviewer, and one copy at headquarters. These records were being maintained on file for at least two years.

The internal reviewers were reporting their findings to Dr. Robert Huey, Divisional Veterinary Officer, Policy, who would, in case of serious noncompliance, pay a personal visit to the establishment the same or the next day. All U.S.-eligible product produced on the day of the unacceptable evaluation would be retained pending Dr. Huey's visit and evaluation. Dr. Huey had full authority up to and including withdrawal of U.S. certification.

After observing one of the internal reviewers' activities in the field, the auditor was confident in his professionalism, thoroughness, and knowledge of U.S. requirements, and in the effectiveness of Northern Ireland's internal review program as a whole.

### Enforcement Activities

Northern Ireland had developed a full system of enforcement capability, which was well documented in an information packet entitled Veterinary Services Prosecutions Policy, which was available to the general public. This contained summaries of official DADRNI enforcement activities and actions.

### Exit Meetings

An exit meeting was conducted in Belfast on May 23. The Northern Irish participants were: Dr. Bert Houston, Deputy Chief Veterinary Officer; Dr. Colin Hart, Senior Principal Veterinary Officer; Dr. Robert Huey, Divisional Veterinary Officer; Dr. Pat Treanor, Divisional Veterinary Officer; Dr. John McEvoy, Veterinary Research Officer, Residues Laboratory; Dr. Glenn Kennedy, Senior Veterinary Research Officer II, Biochemistry; Mr. Gerry McCracken, Principal Officer; and Dr. Gary D. Bolstad, International Audit Staff Officer, FSIS. The audit findings were discussed:

1. Several instances of inadequate cleaning of product-contact equipment prior to pre-operational sanitation inspection were observed. All affected equipment was cleaned and sanitized before operations were begun.
2. Numerous examples of deteriorated product-contact equipment, in need of repair or replacement, were found to be in use. Establishment officials agreed to implement a policy of improved maintenance and monitoring, and replacement where necessary.



3. No formal pre-shipment reviews were being conducted as required. The auditor explained the requirement in detail; DARDNI officials gave assurances that they would ensure that establishment compliance would be implemented promptly and verified regularly.
4. The system in effect did not ensure timely re-sampling of water for potability in the event of noncompliant water samples. An improved, more reliable system was developed and implemented within several days of the establishment audit.
5. Documentation of operational sanitation activities in the establishment was in need of improvement: establishment officials agreed to correct this immediately.

### CONCLUSION

The inspection system of Northern Ireland was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments.

The controls for maintenance and cleaning of product-contact equipment prior to the start of operations in the sole establishment listed, at the time of this audit, as eligible to produce product eligible for export to the United States, were found to have been ineffective and in need of considerable improvement. The establishment was evaluated as acceptable/re-review. The deficiencies encountered during the on-site establishment audits were adequately addressed to the auditor's satisfaction.

Dr. Gary D. Bolstad  
International Audit Staff Officer

(Signed) Dr. Gary D. Bolstad

## **ATTACHMENTS**

- A. Data collection instrument for SSOPs
- B. Data collection instrument for HACCP programs

### Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1. Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
9014	√	√	√	√	√	√	√*	√

7\* Pre-operational sanitation activities were adequately documented, but documentation of operational sanitation activities needed improvement.

### Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. (except Est. 12, which was a cold-storage facility) was required to have developed and implemented a Hazard Analysis – Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis.
3. The analysis includes food safety hazards likely to occur.
4. The analysis includes the intended use of or the consumers of the finished product(s).
5. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
6. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
7. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
8. The plan describes corrective actions taken when a critical limit is exceeded.
9. The HACCP plan was validated using multiple monitoring results.
10. *The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.*
11. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
12. The HACCP plan is dated and signed by a responsible establishment official.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. All hazards identified	4. Use & users included	5. Plan for each hazard	6. CCPs for all hazards	7. Monitoring is specified	8. Corr. actions are described	9. Plan validated	10. Adequate verific. procedures	11. Adequate documentation	12. Dated and signed
9014	√	√	√	√	√	√	√	√	√	√	√	√

No formal pre-shipment reviews were being conducted as required. The auditor explained the requirement in detail; DARDNI officials gave assurances that they would ensure that establishment compliance would be implemented promptly and verified regularly.